

REMARKS

The non-final Office Action mailed 04/29/2004 has been received and carefully reviewed. Claims 1-60 are pending in the patent application. Claims 1-4, 6-13, 19-33, 37-51 and 54-60 stand rejected, and claims 5, 14-18, 34-36 and 52 are objected to, but are indicated as being directed to allowable subject matter. Claims 21 and 54 have been amended. Upon entry of this Response, claims 26-30 and 56 are cancelled without prejudice, and new claims 61-65 have been added. New claims 61-65 are directed to the allowable subject matter of claims 26-30, now canceled.

Reconsideration of the application as amended, and withdrawal of the present rejections are respectfully requested in view of the amendments to the claims and the following remarks.

Claims 1-4, 6-13, 19-20, 43-51 and 53 stand rejected under 35 U.S.C. § 102(b) as being anticipated by *Heil et al.* (U.S. Patent No. 6,304,786).

Applicant respectfully clarifies that *Heil '786* is not assertable under 35 U.S.C. § 102(b). Rather, the *Heil '786* is assertable under paragraph (e) of 35 U.S.C. § 102. Applicant further notes that *Heil '786* and the subject application are, and were at the time of their respective filings, commonly owned by the Assignee.

In rejecting claims 1-4, 6-13, 19-20, 43-51 and 53, the Examiner relies on column 7, line 58 through column 8, line 42 of *Heil '786*. According to this portion of *Heil '786*, coil electrodes 310A-B provide nonuniform, rough peripheral surfaces that allow tissue ingrowth into interstitial regions between the individual coil windings for providing improved fixation. This portion of *Heil '786* further teaches that interelectrode coating 320A partially dissolves after implantation, which also allows tissue ingrowth into the substantially insoluble substrate portion of interelectrode coating 320A.

Applicant's claim 1 recites a sleeve arrangement provided on a lead that includes one or more first locations comprising a first material that substantially prevents cardiac tissue in-growth and one or more adhesion sites provided at the one or more first locations that promote cardiac tissue in-growth or attachment.

Respectfully, *Heil '786* does not teach Applicant's sleeve arrangement recited in claim 1. In particular, *Heil '786* does not teach a sleeve arrangement that has one or more first locations comprising a first material that substantially prevents cardiac tissue in-growth. *Heil '786* also does not disclose one or more adhesion sites that promote cardiac tissue in-growth or attachment provided at the one or more first locations. Rather, both the nonuniform rough peripheral coil electrodes 310A-B and the interelectrode coating 320A taught in *Heil '786* promote tissue ingrowth.

To anticipate a claim, the asserted reference must teach every element of the claim. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. The identical invention must be shown in as complete detail as is contained in the claim. All claim elements and their limitations must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102.

Heil '786 fails to disclose, either expressly or inherently, all the elements of Applicant's independent claims 1 and 43, and dependent claims 2-4, 6-13, 19, 20, 44-51, and 53. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. For at least these reasons, claims 1-4, 6-13, 19, 20, 43-51, and 53 are not anticipated by *Heil '786*.

Claims 21, 54, and 55 stand rejected under 35 U.S.C. §102(b) as being anticipated by *Alfemess '218*. Claims 21 and 54 have been amended to further recite that at least one of the first and second fixation arrangements comprises a spiraled portion of the lead. *Alfemess '218* fails to teach a fixation arrangement

that includes a spiraled portion of the lead. For at least this reason, claims 21, 54, and 55 are not anticipated by *Alfermess '218*.

Claims 22-25 and 56-59 stand rejected 35 U.S.C. § 103(a) as being unpatentable over *Alfermess '218*. Concerning the rejection of these claims, and in view of amended claims 21 and 54, Applicant respectfully asserts that an obviousness rejection of these claims based only on *Alfermess '218* and knowledge possessed by one of ordinary skill in the art at the time of Applicant's filing cannot reasonably be sustained.

To establish *prima facie* obviousness of Applicant's claimed invention, the Examiner has the burden of proving that three basic criteria are met. First, there must be some suggestion or motivation to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicant's disclosure. All three of these criteria must be met in order to support a finding of *prima facie* obviousness of a claimed invention (see, e.g., MPEP § 2142).

Concerning the third criteria which must be met to establish *prima facie* obviousness of a claimed invention, *Alfermess '218* clearly fails to teach or suggest a spiraled portion of the lead that provides for lead fixation. Hence, *Alfermess '218* fails to teach or suggest all of Applicant's features recited in claims 22-25 and 56-59, and amended claims 21 and 54.

In order to supply features missing in *Alfermess '218*, the Examiner tacitly concludes, without reliance on a supporting reference, that the suggested modification to *Alfermess '218* would be obvious to one of ordinary skill in the art because such features are well known means for fixing cardiac leads.

It would appear that the Examiner is impermissibly taking official notice that the elements of Applicant's claims 22-25 and 56-59 and amended claims 21 and 54, in view of the *Alfermess '218*, constitute facts outside of the record which are capable of instant and unquestionable demonstration as being well known or obvious to one skilled in the art. Applicant respectfully disagrees and requests that the Examiner produce a reference that supports the Examiner's assertion that claims 22-25 and 56-59 and amended claims 21 and 54 are obvious.

In determining the differences between the prior art and the claims, the question under 35 U.S.C. § 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. Taking official notice of the above-discussed "facts" disregards the requirement of analyzing Applicant's claimed subject matter "as a whole." Applicant respectfully reiterates the legal tenet that facts so noticed should not comprise the principle evidence upon which a rejection is based. MPEP § 2144.03.

Claims 26-33, 37-42 and 60 stand rejected 35 U.S.C. § 103(a) as being unpatentable over *Alfermess '218* in view of *Heil '786*. As discussed above, *Heil '786* is assertable under paragraph (e) of 35 U.S.C. § 102, and not paragraph (b). Both the subject application and *Heil '786* are assigned to common assignee, Cardiac Pacemakers, Inc. Applicant makes reference to the assignee information provided on the first page of *Heil '786* and the assignee of record information for the instant application recorded at reel 12807, frame 0607 to evidence such common ownership.

The instant application and *Heil '786* were, at the time the invention of *Heil '786* was made, owned by common assignee Cardiac Pacemakers, Inc. Accordingly, *Heil '786* is not a qualified reference under 35 U.S.C. § 102(e) and, therefore, is not available under 35 U.S.C. § 103. As such, *Heil '786* cannot properly be used as a reference to support the Examiner's present rejection of claims 26-33, 37-42 and 60 under 35 U.S.C. § 103(a).

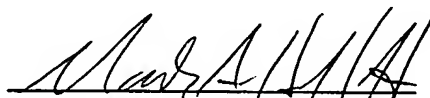
In view of the removal of *Heil* '786 as a qualified reference and the above-made remarks evidencing the inapplicability of the primary reference *Alfermess* '218 to the base claims, claims 26-33, 37-42 and 60 are clearly not rendered obvious by the single reference *Alfermess* '218.

It is believed that the pending are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicant's Representatives, at the below-listed telephone number, if there are any questions regarding the above new claims or if prosecution of this application may be assisted thereby.

Respectfully submitted,
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